DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2015

Synovis Life Technologies Inc.
% Jodi Jorgenson
Manager, Regulatory Affairs
2575 University Ave. W.
St. Paul, Minnesota 55129

Re: K142447
Trade/Device Name: PERI-GUARD Repair Patch
SUPPLE PERI-GUARD Pericardium Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: August 28, 2014
Received: September 2, 2014

Dear Jodi Jorgenson,

This letter corrects our substantially equivalent letter of January 7, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142447

Device Name
SUPPLE PERI-GUARD Pericardium Patch

Indications for Use *(Describe)*
SUPPLE PERI-GUARD is intended for use as a prosthesis for pericardial closure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142447

Device Name
PERI-GUARD Repair Patch

Indications for Use *(Describe)*
PERI-GUARD is intended for repair of pericardial structures. PERI-GUARD is also intended for use as a patch for intracardiac defects, great vessel, septal defects and annulus repair, and suture-line buttressing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY: SUPPLE PERI-GUARD PERICARDIUM PATCH

Applicant:
Synovis Life Technologies, Inc.
(a subsidiary of Baxter International Inc.)
2575 University Avenue West
St. Paul, MN 55114-1024
Tel: 651-796-7300
Fax: 651-642-9018

Contact Person:
Jodi Jorgenson
Manager, Regulatory Affairs
At address above

Date Prepared:
August 28, 2014

Device Trade Name:
SUPPLE PERI-GUARD Pericardium Patch

Common Name:
Intracardiac patch

Classification Name:
Intracardiac patch or pledget
21 CFR 870.3470
Product Code: DXZ

Predicate Devices:
Synovis Life Technologies, SUPPLE PERI-GUARD Pericardium Patch: K983162

Device Description:
SUPPLE PERI-GUARD is prepared from bovine pericardium which is cross-linked with glutaraldehyde. SUPPLE PERI-GUARD has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C. SUPPLE PERI-GUARD is terminally sterilized using gamma irradiation.

SUPPLE PERI-GUARD is packaged between two pieces of foam within a double sterile barrier pouch system. The contents of the unopened, undamaged package are sterile.

Statement of Intended Use:
SUPPLE PERI-GUARD is intended for use as a prosthesis for pericardial closure.

Summary/Comparison of Technological Characteristics:
SUPPLE PERI-GUARD Pericardium Patch is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the packaging and sterilization method, which are the subject of this premarket notification submission.

The safety and performance of SUPPLE PERI-GUARD Pericardium Patch was evaluated through non-clinical testing.

The bench and pre-clinical testing assessed the following aspects of the device:

- Suture retention
- Thickness
- Burst Strength
- Ultimate Tensile Strength
- Collagenase digestion
- Chemical residuals
- Pyrogenicity/ LAL
- Sterilization validation
- Packaging and shelf-life
- Biocompatibility
- Animal studies

Bench testing results support the performance requirements for SUPPLE PERI-GUARD Pericardium Patch. Biocompatibility testing was performed in accordance to ISO 10993-1: 2009 (*Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process).* Various animal studies were conducted to support the safety and efficacy of SUPPLE PERI-GUARD Pericardium Patch. The bench and preclinical studies indicate that the device is biocompatible and is substantially equivalent to the referenced predicate device.

Conclusions:
The safety and performance of SUPPLE PERI-GUARD Pericardium Patch was evaluated through biocompatibility, bench testing and animal studies. SUPPLE PERI-GUARD Pericardium Patch is substantially equivalent to the predicate device.

510(K) SUMMARY: PERI-GUARD REPAIR PATCH

Applicant:
Synovis Life Technologies, Inc.
(a subsidiary of Baxter International Inc.)
2575 University Avenue West
St. Paul, MN 55114-1024
Tel: 651-796-7300
Fax: 651-642-9018

Contact Person:
Jodi Jorgenson
Manager, Regulatory Affairs
At address above

Date Prepared:
August 28, 2014

Device Trade Name:
PERI-GUARD Repair Patch

Common Name:
Intracardiac patch

Classification Name:
Intracardiac patch or pledget
21 CFR 870.3470
Product Code: DXZ

Predicate Devices:
Synovis Life Technologies,
PERI-GUARD Pericardium with Apex Processing: K983162 and K983602

Device Description:
PERI-GUARD is prepared from bovine pericardium which is cross-linked with glutaraldehyde. PERI-GUARD has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C. PERI-GUARD is terminally sterilized using gamma irradiation.

PERI-GUARD is packaged between two pieces of foam within a double sterile barrier pouch system. The contents of the unopened, undamaged package are sterile.

Statement of Intended Use:
PERI-GUARD is intended for repair of pericardial structures. PERI-GUARD is also intended for use as a patch for intracardiac defects, great vessel, septal defects and annulus repair, and suture-line buttressing.

Summary/Comparison of Technological Characteristics:
PERI-GUARD Repair Patch is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the packaging and method of sterilization, which is the subject of this premarket notification submission.

The safety and performance of PERI-GUARD Repair Patch was evaluated through non-clinical testing.

The bench and pre-clinical testing assessed the following aspects of the device:

- Suture retention
- Thickness
- Burst Strength
- Ultimate Tensile Strength
- Collagenase digestion
- Chemical residuals
- Pyrogenicity/ LAL
- Sterilization validation
- Packaging and shelf-life
- Biocompatibility
- Animal studies

Bench testing results support the performance requirements for PERI-GUARD Repair Patch. Biocompatibility testing was performed in accordance to ISO 10993-1: 2009 (*Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process).* Various animal studies were conducted to support the safety and efficacy of PERI-GUARD Repair Patch. The bench and preclinical studies indicate that the device is biocompatible and is substantially equivalent to the referenced predicate device.

Conclusions:
The safety and performance of PERI-GUARD Repair Patch was evaluated through biocompatibility, bench testing and animal studies. PERI-GUARD Repair Patch and is substantially equivalent to the predicate device.